

H.R. 6378, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018

TITLE I: STRENGTHENING THE NATIONAL HEALTH SECURITY STRATEGY

Section 101: National Health Security Strategy

- Clarifies that the National Health Security Strategy should describe potential public health threats facing our nation and identify the processes to prepare to respond to such threats, consistent with other specified plans.
- Incorporates into the Strategy —
 - A description of the current public health workforce and its capabilities to improve medical surge capacity.
 - Considerations for zoonotic disease and disease outbreaks related to food and agriculture.
 - Global health security and environmental hazards as they relate to domestic public health preparedness and response capabilities.

TITLE II: IMPROVING PREPAREDNESS AND RESPONSE

Section 201: Improving Benchmarks and Standards for Preparedness and Response

- Requires the evaluation of existing performance measures, benchmarks, and standards for two core preparedness and response programs, the Public Health Emergency Preparedness (PHEP) cooperative agreement and the Hospital Preparedness Program (HPP).

Section 202: Amendments to Preparedness and Response Programs

- Reauthorizes the PHEP cooperative agreement through 2023. Clarifies that the PHEP cooperative agreement be administered through the Centers for Disease Control and Prevention and updates requirements for the plans required of all PHEP eligible entities.
- Provides additional flexibility for PHEP and HPP awardees to come into compliance with the failure to meet program benchmarks and standards.
- Requires PHEP grantees to include a description of efforts to incorporate health care facilities (i.e. hospitals, nursing homes, and other long-term care facilities), and critical infrastructure partners (i.e. utility companies) in preparing for a public health emergency in their funding applications.
- Reauthorizes HPP through 2023.

Section 203: Regional Health Care Emergency Preparedness and Response Systems

- Requires the Assistant Secretary for Preparedness and Response (ASPR) to develop guidelines within two years, to inform regional systems of hospitals and health care facilities, to treat patients affected by chemical, biological, radiological, or nuclear (CBRN) threats, including emerging infectious diseases, and improve medical surge capabilities and capacity.
- The guidelines will build on lessons learned from the Ebola virus outbreak in 2014 and will provide a roadmap for regions across the country to best leverage their health system infrastructure in the event of a bioterror attack, an emerging infectious disease outbreak, or a pandemic.

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- Allows the ASPR to develop and implement a demonstration project to put the new guidelines developed into practice in regions across the country, which sunsets in 2023.
- Requires the Government Accountability Office (GAO) to report within three years on the progress made towards the implementation of the guidelines by hospitals and health care facilities, and requires subsequent recommendations to address challenges faced during implementation.
- Requires HPP grantees to report on implementation efforts aimed at meeting the capability guidelines.
- Incorporates into the National Health Security Strategy a coordinated and flexible approach to regional health care emergency preparedness and response.
- Encourages PHEP grantees to coordinate with regional health care emergency response capabilities.
- Prioritizes awarding HPP grants to entities that will enhance coordination among one or more facilities in a regional health care emergency system.
- Allows for additional resources authorized under HPP to go toward the new regionalized systems, ensuring existing resources are not taken away from HPP.

Section 204: Military and Civilian Partnership for Trauma Readiness

- Authorizes the Secretary, acting through the ASPR and in consultation with the Secretary of Defense, to award grants to trauma centers to enable military trauma teams to provide trauma care at such centers.
- Requires as a condition of such grants that military trauma providers providing care under such grants be allowed to deploy for military operations or training, and to respond to public health emergencies or mass casualty incidents.
- Integrates military trauma providers at such trauma centers into trainings and drills for public health emergencies.
- Calls for reporting to the Secretaries of HHS and Defense by grantees, as well as to Congress by the Secretaries of HHS and Defense.
- Authorizes appropriations through 2023.

Section 205: Public Health and Health Care System Situational Awareness and Biosurveillance Capabilities

- Directs the GAO to conduct a study on federal spending for Centers for Disease Control and Prevention (CDC) activities related to facility development, and improved capacity and biosurveillance capability for responding to bioterrorism and other public health emergencies.
- Updates and improves CDC's biosurveillance capabilities to advance public health situational awareness by:
 - Updating the use of technical and reporting standards, including interoperability standards for data elements submitted to the biosurveillance network.
 - Improving coordination and collaboration within Health and Human Services (HHS) and across federal agencies and departments through the exchange of data in the biosurveillance network to better inform the situational awareness necessary to monitor, identify, and respond to CBRN threats.
 - Convening a public meeting for public and private stakeholders to improve the development and function of the biosurveillance network.
 - Updating the strategy and implementation plan for the biosurveillance network according

- development and function of the biosurveillance network.
- Updating the strategy and implementation plan for the biosurveillance network according to input from experts, and requiring the Secretary to submit such updates to Congress within two years.
- Establishing an annual budget plan to ensure efficient and effective utilization of resources for the development and improvement of the biosurveillance network.
- Improving coordination with the intelligence community to ensure that the design and capabilities of the network align with the threats facing our nation.
- Authorizes the Secretary to appoint up to 30 specialists at the CDC with expertise in capabilities related to biosurveillance, such as experts in informatics and data analytics.
- Requires the GAO to evaluate and report on activities related to the development and improvement of the biosurveillance network and to provide subsequent recommendations.
- Reauthorizes biosurveillance and situational awareness programs through 2023.
- Requires a report on the state of Federal biological threat detection efforts.

Section 206: Strengthening and Supporting the Public Health Emergency Rapid Response Fund

- To more immediately address the needs resulting from a public health emergency, improves the existing Public Health Emergency Fund (PHEF) by identifying key activities for which PHEF dollars may be used in the context of immediate support for the response activities for a public health emergency or prior to a potential public health emergency.
- Requires the Secretary as well as GAO to conduct a review of the PHEF, including policies that may be needed to improve the PHEF (in the case of the Secretary) and the resources available in such fund and the ability to use such resources during a public health emergency (in the case of GAO) and submit such report to Congress.

Section 207: Improving All-Hazards Preparedness and Response by Public Health Emergency Volunteers

- Further encourages states to develop and implement programs and policies to allow for the licensure of medical professionals to enable them to cross state lines during a public health emergency.
- Encourages states to develop mechanisms to improve the enrollment in, and availability of information regarding, opportunities for volunteer health care professionals seeking to provide medical services during public health emergencies.
- Incorporates into PHEP entities' All-Hazards Public Health Emergency Preparedness and Response Plan a description of how they improve enrollment and coordination of health care professionals seeking to provide medical services during public health emergencies. Clarifies that National Disaster Medical System, Medical Reserve Corps members, and individual practitioners are eligible to enroll in the Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP).
- Advises the Secretary to make public the ways in which states are waiving licensing requirements for health professional volunteers during a public health emergency in order to encourage state and individual participation in ESAR-VHP.
- Reauthorizes ESAR-VHP through 2023.

Section 208: Clarifying State Liability Law for Volunteer Health Care Professionals

- Clarifies the application of state liability law for health care professionals who are members of the Medical Reserve Corps or included in the Emergency System for Advance Registration

- Clarifies the application of state liability law for health care professionals who are members of the Medical Reserve Corps or included in the Emergency System for Advance Registration of Volunteer Health Professionals.
- For such an individual providing health care services in a state with a public health emergency, a major declared disaster or a national emergency, under certain conditions, applies the liability laws of the state for which the emergency has been determined and in which the service is being provided.
- Requires a GAO report on several aspects of health care providers credentialed by in the Emergency System for Advance Registration of Volunteer Health Professionals or state authorities.

Section 209: Report on Adequate National Blood Supply

- Requires a report with recommendations to address challenges with the national blood supply including challenges with recruitment of donors, maintaining the adequacy of the blood supply during a public health emergency, and efforts to promote innovative technologies to improve the blood supply.

Section 210: Report on the Public Health Preparedness and Response Capabilities and Capacities of Hospitals, Long-term Care Facilities, and Other Health Care Facilities

- Requires a report on the public health preparedness and response capabilities for health care facilities, including a review of the effectiveness benchmarks and standards for preparedness programs, an identification of gaps in such benchmarks and standards, and an evaluation of coordination critical infrastructure entities and environmental health agencies.

TITLE III. REACHING ALL COMMUNITIES

Section 301: Strengthening and Assessing the Emergency Response Workforce

- Recent public health emergencies have strained the public health emergency workforce and have highlighted gaps in workforce preparedness. To address these challenges, this section:
 - Includes greater flexibility in pre-positioning response teams in advance of a public health emergency or potential public health emergency.
 - Requires a joint review of the National Disaster Medical System and an assessment of our medical surge capacity relating to the availability of public health workforce for both a widespread and multiple public health emergencies at one time.
 - Improves communication with Congress by requiring the Secretary to notify Congress when the NDMS workforce is insufficient to address a public health emergency, including information on the effect such insufficiencies will have and potential ways to address the issue.
 - Bolsters hiring authorities to allow for faster onboarding of NDMS to decrease the shortage in the health care emergency response workforce.
 - Extends death benefits for NDMS participants that are allotted to other public safety officers, including FEMA volunteers through 2021.
 - Strengthens the recruitment of highly qualified providers to the Epidemic Intelligence Service (EIS) by extending the option of loan repayment for EIS program participants.
 - Requires a GAO report on the capabilities and capacity of the volunteer health care workforce, gaps in such workforce, and recommendations for addressing the gaps.
- Reauthorizes the National Disaster Medical System through 2023.
- Reauthorizes the Medical Reserve Corps through 2023.

Section 302: Health System Infrastructure to Improve Preparedness and Response

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- Building from lessons learned in previous public health emergencies, this section encourages the ASPR to coordinate with public and private-sector partners that provide critical supplies or information to an affected area during a public health emergency or emergency or major disaster declared by the President under the Stafford Act or National Emergencies Act to assist with the response.
- Requires the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to incorporate the need for certain medical supplies to be used with medical countermeasures (MCM) in MCM enterprise planning.
- Directs the Secretary to consider manufacturing capacity and outside sources of medical supplies when replenishing products in the Strategic National Stockpile (SNS).
- Authorizes the ASPR to conduct a study on issues with the potential to adversely affect the handling and rapid delivery of medical countermeasures.

Section 303: Considerations for At-Risk Individuals

- Updates and aligns the term “at-risk individual” across the PAHPA framework to improve considerations, ensure consistency in considerations, and provide clarity throughout the framework.
- Encourages the director of at-risk individuals to incorporate appropriate data and information relevant to detecting emerging public health threats that may affect at-risk individuals, such as pregnant and postpartum women and infants into the existing situational awareness and biosurveillance network at the CDC.

Section 304: Improving Emergency Preparedness and Response Considerations for Children

- Codifies and continues the work of the Children’s Preparedness Unit at the CDC to ensure the needs of children are taken into consideration when preparing for and responding to public health emergencies.

Section 305: National Advisory Committees on Disasters

- Reauthorizes the National Advisory Committee on Children and Disasters through 2023.
- Authorizes a National Advisory Committee on Seniors and Disasters through 2023.
- Authorizes a National Advisory Committee on Individuals with Disabilities in Disasters through 2023.
- Requires the advisory committees to coordinate duties and activities to address the overlapping needs of such individuals and reduce duplicate efforts.

Section 306: Guidance for Participation in Exercises and Drills

- Requires the Secretary to issue final guidance on the participation of federally funded public health personnel in drills and operational exercises for public health emergency preparedness and response.

TITLE IV: PRIORITIZING A THREAT-BASED APPROACH

Section 401: Assistant Secretary for Preparedness and Response

- Clarifies the congressional intent for the ASPR to utilize experience related to biodefense, medical countermeasures, and emergency preparedness and response.
- Encourages the ASPR to coordinate with the intelligence community, and defense and public health officials in developing a strategy to address the threat-based approach to the

medical countermeasures, and emergency preparedness and response.

- Encourages the ASPR to coordinate with the intelligence community, and defense and public health agencies in conducting his or her work to address threats and develop and strengthen our emergency preparedness and response framework.
- Authorizes funding for the Assistant Secretary for Preparedness and Response to implement strategic initiatives or activities related to preparedness and response to pandemic influenza threats.

Section 402: Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- Codifies the PHEMCE, an entity comprised of heads of relevant federal agencies to inform the direction of research, development, stockpiling, utilization, and procurement of MCMs for the SNS, including considerations for deployment and distribution of MCMs.

Section 403: Strategic National Stockpile

- Requires that the Secretary collaborate with both the ASPR and the CDC in the Secretary's management of the stockpile.
- Provides additional direction and a threat-based focus for the existing annual review of the SNS.
- Requires additional information on SNS procurement and replenishment decisions, as well as advanced planning for deployment, distribution, and dispensing for additions to the SNS.
- Requires GAO to review the Secretary's processes and decisions related to procurement of countermeasures for the stockpile and any changes in the federal organizational management of the SNS.
- Reauthorizes the SNS through 2023.

Section 404: Preparing for Pandemic Influenza, Antimicrobial Resistance, and Other Significant Threats

- Provides authorities for the Director of the Biomedical Advanced Research and Development Authority (BARDA) to develop strategic initiatives for threats that pose a significant level of risk to national security.
- These strategic initiatives will accelerate and support advanced research, development, and procurement of countermeasures to address:
 - Threats for which no countermeasure exists, or which may become resistant to current countermeasures or existing countermeasures may be rendered ineffective.
 - Threats that consistently exist or are continually circulating in a human or animal population and have significant potential to become a pandemic, such as pandemic influenza.
 - Certain threats resulting from exposure to a CBRN agent and which may present increased complications in treating a countermeasure resistant disease or condition during a public health emergency, including antimicrobial resistant pathogens.
- Authorizes an Emerging Infectious Disease Program to support advanced research and development activities for qualified pandemic or epidemic products with respect to an emerging infectious disease.

Section 405. Reporting on the Federal Select Agent Program

- Requires the Secretary to report on the implementation of recommendations from the Federal Experts Security Advisory Panel and the Fast Track Action Committee regarding improvements to the Select Agent Program.

TITLE V: INCREASING COMMUNICATION IN MCM ADVANCED RESEARCH AND DEVELOPMENT

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Section 501: Medical Countermeasure Budget Plan

- Updates the Countermeasure Budget Plan to include considerations for manufacturing capabilities and capacity for MCMs, information on new and innovative technologies that may support the research and development of MCMs, to improve the communication on areas of priority for MCM development, and provide information related to potential the deployment, distribution, and utilization of medical countermeasures.

Section 502: Material Threat and Medical Countermeasure Notifications

- Requires the Secretaries of HHS and Department of Homeland Security (DHS) to notify the Health, Education, Labor and Pensions Committee of the Senate, the Security and Government Affairs Committee of the Senate, and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives of current material threat determinations on an annual basis, and promptly notify Congress each time there is a change to such determinations.
- Requires the Secretary to notify a manufacturer of a MCM within 90 days, regarding the Secretary's decision to award, extend, renew or terminate agreements related to the purchase of MCMs for the stockpile.

Section 503: Availability of Regulatory Management Plans

- Requires the Food and Drug Administration (FDA) to post on the Internet the processes and information necessary for potential MCM sponsors to apply for a regulatory management plan to raise awareness of the use of the plans for MCMs.

Section 504: BARDA and the Bioshield Special Reserve Fund

- Reauthorizes BARDA through 2023.
- Reauthorizes the BioShield Special Reserve Fund through 2028.

Section 505. Additional Strategies for Combating Antibiotic Resistance.

- Codifies the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria to advise the Secretary on efforts to reduce or combat antibiotic-resistant bacteria that may present a public health threat and provide input to improve capabilities to prevent, diagnose, mitigate, or treat such resistance.

TITLE VI: ADVANCING TECHNOLOGIES FOR MEDICAL COUNTERMEASURES

Section 601: Administration of Countermeasures

- Clarifies BARDA's ability to use existing resources toward the development of technologies intended to assist in the administration of countermeasures.

Section 602: Updating Definitions of Other Transactions

- Clarifies the authority of the BARDA Director to utilize other transactions authorities to further the advanced research and development of medical countermeasures.

Section 603: Medical Countermeasure Master Files

- Establishes a clear process for submitting information and data on technologies into a Master File that may be incorporated into a future application to support a MCM product. A product sponsor, either the submitter of information or another person with right of reference, may utilize this information and data as a part of their MCM application, and build upon that data

File that may be incorporated into a future application to support a MCM product. A product sponsor, either the submitter of information or another person with right of reference, may utilize this information and data as a part of their MCM application, and build upon that data for future MCM applications.

- Requires FDA to notify the Master File holder when the agency has referenced the technology in the Master File – clarifying that the same data and information can support future MCM applications.
- Requires FDA to publish draft guidance, within three years, on the reliance and use of data and information included in the Master Files to support and accelerate the development of countermeasures.

Section 604: Animal Rule Report

- Requires the GAO to consult federal agencies, manufacturers, and other biodefense stakeholders to inform a report within three years on the use of the animal rule in the development of MCMs, and if applicable make recommendations to support and speed the research and development of MCMs.

Section 605: Review of the Benefits of Genomic Engineering Technologies and Their Potential Role in National Security

- Requires the Secretary of HHS to convene a meeting with federal partners and private entities to discuss the potential role advancements in genomic engineering technologies (including genome editing technologies) may have in advancing national health security.
- Not later than 270 days after such meeting, the ASPR will issue a report detailing the discussion and providing recommendations to utilize innovation in this technology to advance national health security.

Section 606: Report on Vaccines Development

- Requires a report on previous efforts to coordinate with other countries during public health emergencies to conduct advanced research and development of qualified pandemic or epidemic products, including the development of products through public-private partnerships.

Section 607: Strengthening Mosquito Abatement for Safety and Health (SMASH)

- Reauthorizes critical public health tools that support states and localities in their mosquito surveillance and control efforts, especially those linked to vector-borne diseases like the Zika virus.
- Renews epidemiology-laboratory capacity grants administered by CDC that provide support for surveillance and response capabilities for infectious diseases at the local level.

TITLE VII: REAUTHORIZATIONS AND TECHNICAL CHANGES

Section 701: Reauthorizations and Extensions

- Reauthorizes funding for influenza vaccine tracking and distribution during an influenza pandemic.
- Reauthorizes the temporary reassignment authority through 2023.
- Reauthorizes the MCM innovation partner through 2023, to align with the authorized timelines in this Act.
- Extends the limited antitrust exemption.
- Clarifies the limitations on the disclosure of certain scientific or technical information developed during medical countermeasure research.

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Section 702: Location of Materials in the Stockpile

- Updates and clarifies the limitations on the disclosure of certain information pertaining to the Strategic National Stockpile with the potential to affect national security.

Section 703: Cybersecurity

- Requires the development of a national strategy for public health preparedness and response to address cybersecurity threats that present a threat to national health security.
- Clarifies the role of the ASPR as it relates to cyber incidents that present a threat to national health security.

Section 704: Technical Changes

- Technical amendments to the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act.

Section 705: Formal Strategy for Reunification

- Requires a formal strategy to reunite each child with their parent or guardian where they have been separated as a result of the “zero tolerance” policy.

Section 706: Report on Reunification

- Requires a report on the status of the work conducted by the ASPR to reunite each child with their parent or guardian where they have been separated as a result of the “zero tolerance” policy.

Section 707: Technical Correction

- This technical correction to section 704 of the FDA Reauthorization Act of 2017, will ensure medical device manufacturers can obtain “certificates to foreign governments” whether they are located inside or outside the U.S., as was intended by Congress.

Section 708: Savings Clause

- Sets forth that nothing in this Act reduces or limits authorities vested in other Federal Agencies.